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K002205

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ABBREVIATED 510(k)
PREMARKET NOTIFICATION SUBMISSION
510(k) SUMMARY OF SAFETY AND EFFICACY

General Information:

Submitter's Name:	Bruno Independent Living Aids
Address:	PO Box 84 1780 Executive Drive Oconomowoc, WI 53066
Telephone:	(800) 882-8183
Contact Person:	Richard Keller
Telephone:	(262) 953-5336
e-mail:	dick.keller@bruno.com

Date Prepared: July 10, 2000

FDA Registration Number: 2131358

Name of the Device:	Carony
Trade Name:	Carony Wheelchair, Carony System
Common Name of the Device:	Manual Wheelchair, Transport Wheelchair
Device Classification Name:	Wheelchair, Mechanical
Panel Code of the Device:	IOR
Classification of the Device:	Class I
Regulation Number:	890.3850

Identification of Predicate Devices:

K000497 Voyager/Viper wheelchair by Otto Bock Orthopedic Industry, Inc.
K983639 Zippie GS wheelchair by Sunrise Medical, Inc.

Description of the Device:

The Carony wheelchair consists of a seat and a mechanical wheelchair mobility base to provide mobility to a mobility-impaired person. The Carony wheelchair is part of a system that provides simplified transferring of mobility-impaired persons into and out of private motor vehicles.

The wheelchair is manufactured in Boras, Sweden, at a division of autoADAPT/BEV known as BEV Euroaid AB. The Carony is sold in Europe as "Carony". It will also be marketed and sold in the United States as "Carony".

The wheelchair seat is based upon an automotive-style aftermarket seat, typical of many wheelchair seats, with added features providing the ability to dock with a private motor

vehicle and slide from the wheelchair mobility base into the vehicle. For added comfort, the seat has an adjustable back angle, adjustable-height headrest and adjustable armrests. The central padded, upholstered portion of the seating and backrest surfaces can be removed for cleaning or may be replaced by pressure-reduction cushions from other medical equipment suppliers, as required.

The mechanical wheelchair mobility base provides the wheeled mobility function, typical of most wheelchairs, to the seat. The wheelchair mobility base is a rigid frame, non-folding wheelchair that provides removable handles for pushing by an attendant, manual wheel locks for parking the wheelchair, and legrests for foot support. In addition, it also features a mechanical elevating system to vertically adjust the seat height (115mm) to match the motor vehicle height, permitting easy docking of the seat with, and sliding into, the vehicle.

The seat is manufactured with a steel frame, vinyl and fabric upholstery, and foam rubber padding. This is common construction for many wheelchair seats.

The mechanical wheelchair mobility base structure is manufactured from powder-coated steel tubing, which is welded. The wheels are molded plastic with pneumatic tires. Other hardware items are plastic covers for the mechanisms and appearance, nylon gears in the elevating system, and steel wire-formed levers. This is common construction for mechanical wheelchairs.

Statement of Intended Use:
The Carony is intended to provide wheeled mobility for mobility-impaired persons while in a sitting position.

Technological Characteristics Summary:
The wheelchair construction is substantially equivalent to:
Voyager/Viper wheelchair, decision date 03/08/2000, K000497 (Section 18) and
Zippie GS wheelchair, decision date 10/25/1998, K983639 (Section 19)

Testing to an FDA Recognized Consensus Standard:
Handikappinstitutet Testing Laboratory, Vallingby, Sweden, tested the Carony to applicable FDA Recognized Consensus Standards Appendix A.
The standards tested to are:
ISO7176-1:1986, Determination of Static Stability
ISO7176-3:1988, Determination of Efficiency of Brakes
ISO7176-5:1986, Determination of Overall Dimension, Mass and Turning Space

Test results reported are:
ISO7176-1:1986, device is in compliance
ISO7176-3:1988, device is in compliance
ISO7176-5:1986, device is in compliance

Flammability tests were performed by SP, *Sveriges Provnings*, Boras, Sweden, for the Carony armrests and by Zelu Chemie in Murr, Germany for the seat per:
FMVSS302/ISO3795, Flammability of Interior Materials*

ISO7176-16 listed in the FDA Recognized Consensus Standards Appendix A specifies requirements and methods of test to assess the resistance to ignition by cigarettes and match of the materials used in wheelchair upholstered parts.
FMVSS302/ISO3795 (identical standards) specifies burn resistance requirements for materials used in the occupant compartment of automobiles. This standard is more severe than ISO7176-16, resulting in use of materials with superior flame resistance (compared with ISO7176-16) in the wheelchair seat.
*note: Since this is an automotive-type seat and since it is occupied while in a motor vehicle, the FMVSS302/ISO3795 standard is more appropriate than ISO7176-16, and required by USDOT/FMVSS, for the seat and armrest flammability test.

Test results reported are:
FMVSS302/ISO3795, device is in compliance

Additional Testing to International Standards:
Additional tests cited by the Handikappinstitutet Testing Laboratory in their report are:
ISO7176-7 (HI Test Method R002), Determination of Seating and Wheel Dimensions
ISI7176-8, Determination of Static Strength,
Determination of Impact Strength,
Fatigue Strength Test in Double Drum,
Fatigue Strength Test in Kerb Drop Tester
HI Test Method R005, Determination of Tracking Characteristics
PrEN 12183, Determination of Pushing Force, Fatigue Strength for Parking Brakes

Test results reported are:
ISO7176-7 (HI Test Method R002), device is in compliance
ISI7176-8, device is in compliance
HI Test Method R005, device is in compliance
PrEN 12183, device is in compliance

Comparison of Device Standards Compliance to Predicates:

Carony	Zippie GS, K983639	Voyager/Viper, K000497
ISO7176-1	ISO7176-1	ISO7176-1
ISO7176-3		ISO7176-3
ISO7176-5	ISO7176-5	
ISO7176-7	ISO7176-7	
ISO7176-8	ISO7176-8	ISO7176-8
FMVSS302/ISO3795*		ISO7176-16

Conclusion: The Carony wheelchair shares the same Recognized Consensus Standards compliance and Technological Characterisitics with devices already legally marketed in the United States.

Signed Richard A. Keller, III

Richard A. Keller, III

Date July 17, 2000

Premarket Notification 510(k) Number K002205

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Richard Keller
Product Development Manager
Bruno Independent Living Aids, Inc.
1780 Executive Drive
Oconomowoc, Wisconsin 53066

Re: K002205
Trade Name: Carony Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: July 17, 2000
Received: July 21, 2000

Dear Mr. Keller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Barbara Zimmerman for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K002205

Device Name: Carony

Indications for Use: The Carony is intended to provide wheeled mobility for a mobility-impaired person while in a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ~~ANOTHER~~ PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Over-the-Counter Use X

Barbara [illegible] for (MW)
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002205